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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,454	08/02/2000	Hungming J. Liaw	1533.0730001/SRL/TBB	9071
26111	7590	12/28/2004	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/630,454	Applicant(s) LIAW ET AL.	
	Examiner S. Devi, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 12-16 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-16 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 9 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 08/03/04 in response to the non-final Office Action mailed 03/09/04.

Status of Claims

- 2) Claims 12-16 have been amended via the amendment filed 08/03/04.
Claims 9 and 12-16 are pending and are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Withdrawn

- 5) The rejection of claim 9 made in paragraph 11 of the Office Action mailed 03/09/04 under 35 U.S.C. § 102(b) as being anticipated by Hsiao *et al.* (*Biotechnol. Bioengineer.* 49: 341-347, 1996, already of record), is withdrawn in light of Applicants' argument that Hsiao's Figures 1 and 2 report the production of L-lysine in an amount greater than about 10 g/l only after approximately 30 hours and 40 hours respectively.

Rejection(s) under 35 U.S.C. § 102

- 6) Claim 9 is rejected under 35 U.S.C. § 102(b) as being anticipated by Nakanishi *et al.* (US 4,657,860, already of record).

The term 'raffinate' is interpreted in this rejection as containing a large amount of ammonia sulfate, amino acids, various salts, and carbohydrates. See lines 4-6 on page 7 and lines 2 and 3 on page 8 of the specification.

Nakanishi *et al.* disclosed a *Corynebacterium* strain which produces about 34 to 36 g/l of L-lysine in 24 hours when grown in a bacterial culture medium containing at least 1% raffinate, i.e., glucose, ammonium sulfate, various salts, and soybean meal (inclusive of amino acids). See

Example 2 and Table 2.

Claim 9 is anticipated by Nakanishi *et al.*

Rejection(s) under 35 U.S.C. § 103

7) Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hsiao *et al.* (*Biotechnol. Bioengineer.* 49: 341-347, 1996, already of record) in view of Nakanishi *et al.* (US 4,657,860, already of record).

The term raffinate is interpreted in this rejection as a wastestream product from an ion-exchange operation for lysine recovery (see lines 21-23 on page 13 of the specification).

Hsiao *et al.* taught an isolated auxotrophic *Corynebacterium* which produces grams per liter of L-lysine about 30 hours into the bacterial culture in a culture medium containing glucose, $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, K_2HPO_4 , KH_2PO_4 , amino acids, sugar from beet molasses, at least 4% ammonium sulfate, and additional ammonium sulfate from an autoclaved recycling broth effluent containing some L-lysine from a cation exchange for L-lysine (i.e., a wastestream product from an ion-exchange operation for lysine recovery). The production of L-lysine was evident after 20 hr. of cultivation. See 'Materials and Methods'; 'Results and Discussion'; Figure 1; and Table I and II.

Hsiao's *Corynebacterium* strain does not appear to produce at least 10 grams of L-lysine in 24 hours.

However, a *Corynebacterium* strain which produced as high as about 34 to 36 g/l of L-lysine in 24 hours was already known in the art at the time of the invention. For example, Nakanishi *et al.* disclosed a *Corynebacterium* strain which produced about 34 to 36 g/l of L-lysine in 24 hours when grown in a bacterial culture medium containing glucose, ammonium sulfate, various salts, and soybean meal (inclusive of amino acids). See Example 2 and Table 2. Nakanishi *et al.* further disclosed that L-lysine, one of the essential amino acids, has a great demand as a medicament, additive to animal feed, or food, and identified a need in the art for a process of producing L-lysine at an industrially low cost and at a rapidly increased productivity (see third and fifth full paragraphs in column 1).

Given the identified need in the art for a process of rapidly increasing the productivity of L-lysine at low cost, an essential amino acid with a great demand as a medicament, additive to animal feed, or food as taught by Nakanishi *et al.*, it would have been *prima facie* obvious to one

of ordinary skill in the art at the time the invention was made to replace Hsiao's *Corynebacterium* strain with Nakanishi's *Corynebacterium* strain which was already demonstrated in the art to be a high L-lysine producing strain to produce the instant invention with a reasonable expectation of success. Given that Nakanishi's strain was already demonstrated in the art to produce as high as about 34 to 36 g/l of L-lysine in 24 hours, one of skill in the art would have been motivated to produce the instant invention for the expected benefit of producing higher amounts of L-lysine in a shorter time since there was a need in the art to produce L-lysine at an industrially low cost as taught by Nakanishi *et al.* The substitution of one *Corynebacterium* strain with another, alternative, art-known *Corynebacterium* strain, which was already shown in the art to be a better producer of L-lysine, was well within the realm of routine experimentation, and would have been obvious to a skilled artisan.

Claim 9 is *prima facie* obvious over the prior art of record.

Remarks

- 8) Claim 9 stands rejected. Claims 12-16 are allowable.
- 9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses or papers is (571) 273-8300.
- 10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which

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would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER